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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EISAI R&D MANAGEMENT CO., LTD.;
EISAI CO., LTD.;
EISAI MANUFACTURING LTD.;
EISAI INC.; and
MSD ONCOLOGY HOLDINGS LTD,

Plaintiffs,

v.

SHILPA MEDICARE LIMITED,

Defendant.

Civil Action No. 19-19998

Document Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Eisai R&D Management Co., Ltd., Eisai Co., Ltd., Eisai Manufacturing Ltd., and Eisai Inc. (collectively, "Eisai"), and MSD Oncology Holdings Ltd (together with Eisai, "Plaintiffs"), for their Complaint against Defendant Shilpa Medicare Limited ("Defendant"), hereby allege as follows:

THE PARTIES

1. Plaintiff Eisai R&D Management Co., Ltd. ("ERDC") is a Japanese corporation

having a principal place of business at 6-10 Koishikawa 4-Chome, Bunkyo-ku, Tokyo 112-8088, Japan.

2. Plaintiff Eisai Co., Ltd. ("ECL") is a Japanese corporation having a principal place of business at 6-10 Koishikawa 4-Chome, Bunkyo-ku, Tokyo 112-8088, Japan.

3. Plaintiff Eisai Manufacturing Ltd. ("EML") is an English and Welsh corporation having a principal place of business at European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire AL10 9SN, U.K.

4. Plaintiff Eisai Inc. ("ESI") is a Delaware corporation having a principal place of business at 100 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

5. Plaintiff MSD Oncology Holdings Ltd ("MSD") is an English and Welsh private limited company having a principal place of business at Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, U.K.

6. Upon information and belief, Defendant Shilpa Medicare Limited ("Shilpa") is an Indian corporation having a principal place of business at #12-6-214/A1, Hyderabad Road, Raichur – 584 135, Karnataka, India.

7. Upon information and belief, Defendant Shilpa develops, manufactures, markets, distributes, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

JURISDICTION AND VENUE

8. This is a civil action for infringement of United States Patent No. 10,259,791 ("the '791 patent" or "the patent-in-suit"). This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

9. This Court has jurisdiction over the subject matter of this action pursuant to

28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 35 U.S.C. § 271. This Court may declare the rights and other legal relations of the parties under 28 U.S.C. §§ 2201-2202 because this case is an actual controversy within the Court's jurisdiction.

10. Venue is proper in this Court as to Shilpa under 28 U.S.C. §§ 1391(c)(3) and 1400(b) because Shilpa is a foreign corporation and may be sued in any judicial district in the United States, in which Shilpa is subject to the court's personal jurisdiction. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

11. This Court has personal jurisdiction over Shilpa, and venue is proper as to Shilpa, because, *inter alia*, Shilpa: (1) has purposely availed itself of the privilege of doing business in New Jersey, directly or indirectly through its subsidiary, agent, and/or alter ego; (2) maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey; (3) upon information and belief, derives substantial revenue from the sale of its products in New Jersey; and (4) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute Shilpa's ANDA Products (as defined in paragraph 21, *infra*).

12. This Court has personal jurisdiction over Shilpa because, *inter alia*, Shilpa has committed, aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement, including acts in the State of New Jersey, that have led to foreseeable harm and injury to Plaintiffs in the State of New Jersey.

13. Shilpa sent ERDC and ESI a Paragraph IV Notice Letter (as defined in paragraph 22, *infra*) dated June 18, 2019 stating that Shilpa had filed Abbreviated New Drug Application

("ANDA") No. 213094 seeking approval from the United States Food and Drug Administration ("FDA") to commercially manufacture, use, market, or sell generic lenvatinib mesylate oral capsules, EQ 4 mg base and EQ 10 mg base, in the United States (including, upon information and belief, in the State of New Jersey), prior to the expiration of the '791 patent. ESI received Shilpa's Paragraph IV Notice Letter in the State of New Jersey**.**

14. This Court has personal jurisdiction over Shilpa because, *inter alia*, it has availed itself of the legal protections of the State of New Jersey by previously consenting to personal jurisdiction in this Judicial District. *See, e.g.*, *Celgene Corp. v. Shilpa Medicare Ltd.*, 18-11157 (D.N.J. June 27, 2018).

15. Alternatively, should the Court find that the above facts do not establish personal jurisdiction over Shilpa in this action, this Court may exercise jurisdiction over Shilpa pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Plaintiffs' claims arise under federal law; (2) Shilpa is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Shilpa has sufficient contacts with the United States as a whole, including, but not limited to, submitting various ANDAs to the FDA and manufacturing, importing, offering to sell, or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Shilpa satisfies due process.

THE PATENT-IN-SUIT

16. ESI holds approved New Drug Application ("NDA") No. 206947, which the FDA approved on February 13, 2015. ESI markets and sells the oral capsules that are subject of NDA No. 206947 in the United States under the brand name "LENVIMA®." The LENVIMA® labeling states that "LENVIMA capsules for oral administration contain 4 mg or 10 mg of lenvatinib, equivalent to 4.90 mg or 12.25 mg of lenvatinib mesylate, respectively."

17. LENVIMA® has been approved by the FDA for four indications. First, on February 13, 2015, the FDA approved LENVIMA® for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer. As part of this FDA approval, Eisai received Orphan Drug Exclusivity, which expires February 13, 2022. Second, on May 13, 2016, the FDA approved LENVIMA® in combination with everolimus for the treatment of patients with advanced renal cell carcinoma following one prior anti-angiogenic therapy. Third, on August 15, 2018, the FDA approved LENVIMA® for the first-line treatment of patients with unresectable hepatocellular carcinoma. As part of this FDA approval, Eisai received Orphan Drug Exclusivity, which expires August 15, 2025. Fourth, on September 17, 2019, the FDA approved LENVIMA® in combination with pembrolizumab, for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation.

18. ERDC is the assignee of the ’791 patent. ECL is an exclusive licensee of the ’791 patent. EML and MSD are co-exclusive sub-licensees of the ’791 patent. ESI is a wholly-owned, indirect subsidiary of ECL and markets and sells LENVIMA® in the United States.

19. The ’791 patent was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on April 16, 2019, and is titled “High-Purity Quinoline Derivative and Method for Manufacturing Same.” A copy of the ’791 patent is attached as Exhibit A.

20. Pursuant to 21 U.S.C. § 355(b)(1), the ’791 patent is listed in the FDA’s publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the “Orange Book”) as covering Plaintiffs’ LENVIMA®.

SHILPA'S ANDA AND NOTICE LETTER

21. Upon information and belief, Shilpa submitted ANDA No. 213094 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation in the United States, of generic lenvatinib mesylate oral capsules, EQ 4 mg base and EQ 10 mg base ("Shilpa's ANDA Products"), prior to the expiration of the '791 patent. Upon information and belief, Shilpa's ANDA No. 213094 contains a certification with respect to the '791 patent under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification").

22. Upon information and belief, on or about June 18, 2019, Shilpa sent a letter providing notice of Shilpa's Paragraph IV Certification ("Shilpa's Paragraph IV Notice Letter") with respect to the '791 patent to ERDC and ESI, which ESI received in the State of New Jersey. In its Paragraph IV Notice Letter, Shilpa represented that ANDA No. 213094 included a Paragraph IV Certification with respect to the '791 patent, and that Shilpa sought approval of ANDA No. 213094 prior to the expiration of the '791 patent.

23. Shilpa's Paragraph IV Notice Letter included an Offer of Confidential Access ("OCA"), which proposed to limit Plaintiffs' access to only selected information from Shilpa's ANDA No. 213094. Plaintiffs responded to Shilpa's OCA by requesting access to a complete copy of Shilpa's ANDA No. 213094 and samples of Shilpa's ANDA Products. Plaintiffs' request was made pursuant to FDCA, 21 U.S.C. § 355(j)(5)(C)(i)(III), which permits restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. Shilpa, however, refused Plaintiffs' requests and their

attempts to negotiate confidential access. As a result, Shilpa withheld from Plaintiffs Shilpa's ANDA No. 213094 and samples of Shilpa's ANDA Products.

ACTS GIVING RISE TO THIS ACTION

INFRINGEMENT BY SHILPA

24. Plaintiffs re-allege paragraphs 1-23 as if fully set forth herein.

25. By seeking approval of ANDA No. 213094 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Shilpa's ANDA Products prior to the expiration of the '791 patent, Shilpa has infringed one or more claims of the '791 patent under 35 U.S.C. § 271(e)(2)(A).

26. Upon information and belief, the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Shilpa's ANDA Products meets or embodies all elements of one or more claims of the '791 patent.

27. Upon information and belief, Shilpa intends to and will engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Shilpa's ANDA Products upon receipt of final FDA approval of ANDA No. 213094.

28. If Shilpa manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States, Shilpa's ANDA Products prior to the expiration of the '791 patent, Shilpa will infringe one or more claims of the '791 patent under 35 U.S.C. §§ 271(a), (b), (c) or (g).

29. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of Shilpa's ANDA No. 213094 be a date that is not earlier than the expiration date of the '791 patent, or any later expiration of any

patent term extension or exclusivity for the '791 patent to which Plaintiffs are or become entitled.

30. Plaintiffs are entitled to a declaration that, if Shilpa commercially manufactures, uses, offers for sale, or sells Shilpa's ANDA Products within the United States, imports Shilpa's ANDA Products into the United States, or induces or contributes to such conduct, Shilpa will infringe the '791 patent under 35 U.S.C. §§ 271(a), (b), (c), or (g).

31. Plaintiffs will be irreparably harmed by Shilpa's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that the Court grant the following relief:

A. A Judgment decreeing that Shilpa has infringed the '791 patent by submitting ANDA No. 213094;

B. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283 restraining and enjoining Shilpa, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with Shilpa, from infringing the '791 patent by the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Shilpa's ANDA Products;

C. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 213094 be a date that is not earlier than the expiration date of the '791 patent, or any later expiration of any patent term extension or exclusivity for the aforementioned patent to which Plaintiffs are or become entitled;

D. An award of monetary relief to the extent Shilpa commercially manufactures, uses, offers to sell, or sells within the United States, or imports into the United States any product

that infringes or induces or contributes to the infringement of the '791 patent within the United States prior to the expiration of the aforementioned patent, including any later expiration of any patent term extension or exclusivity for the patent to which Plaintiffs are or become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest; and

E. Such other and further relief as the Court may deem just and proper.

Dated: November 8, 2019

s/ William P. Deni, Jr.

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